# PATENT COOPERATION TREATY

# PCT



## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference P10349WO | FOR FURTHER ACTION | See Form PCT/IPEA/416 |
|---|---|---|
| International application No. PCT/GB2005/000223 | International filing date *(day/month/year)* 24.01.2005 | Priority date *(day/month/year)* 23.01.2004 |
| International Patent Classification (IPC) or national classification and IPC A61M5/20, A61M5/30 | | |
| Applicant THE MEDICAL HOUSE PLC et al. | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 7 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

| | | |
|---|---|---|
| ☒ | Box No. I | Basis of the opinion |
| ☐ | Box No. II | Priority |
| ☐ | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ | Box No. IV | Lack of unity of invention |
| ☒ | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☐ | Box No. VI | Certain documents cited |
| ☒ | Box No. VII | Certain defects in the international application |
| ☒ | Box No. VIII | Certain observations on the international application |

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 20.10.2005 | 23.01.2006 |
| Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Reinbold, S Telephone No. +49 89 2399-7918 |

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

International application No.
PCT/GB2005/000223

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

| | |
|---|---|
| **Description, Pages** | |
| 1-26 | as originally filed |
| **Claims, Numbers** | |
| 1-32 | received on 25.10.2005 with letter of 20.10.2005 |
| **Drawings, Sheets** | |
| 1/27-27/27 | as originally filed |

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

## Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 1-32 |
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | 1-32 |
| | No: | Claims | |
| Industrial applicability (IA) | Yes: | Claims | 1-32 |
| | No: | Claims | |

2. Citations and explanations (Rule 70.7):

**see separate sheet**

## Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

## Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:
   D1: US 6544234
   D2: WO 03097133
   D3: US 5681291
   D4: WO 0009186

**Novelty Article 33(2) PCT and Inventive Step Article 33(3) PCT**

2. The present application does appear to meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1-32** is new and inventive in the sense of Article 33(2) and (3) PCT.

   The document D1 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) an injection device (10) comprising (figures 1-19) an outer housing (50) inside which is located:
   - a barrel (12)
   - a needle (18) at one end of the barrel, the needle (18) and barrel (12) being such that at least part of the needle is axially moveable in and out of said outer housing (50) but is biased to be normally wholly inside said housing
   - a plunger (28)
   - an inner housing (96) intermediate the outer housing and the barrel and plunger
   - an energy source (94) in communication with said inner housing (96)
   - wherein the inner housing (96) is moveable by the energy source between three positions, namely:
     - a first position (Fig.4) in which the inner housing has one or more radially flexible tags (100) which are in communication with the barrel (30+36) such that, in use, the plunger and barrel are moveable axially so as to move at least part of said needle out of the outer housing
     - a second position in which said plunger is moveable axially into said barrel so as to expel medicament through the needle

- a third position in which the plunger and barrel are able to retract in order to retract the needle into the outer housing

The subject-matter of claim 1 therefore differs from this known device in that:
- the inner housing is moveable between three positions, namely:
  - a second position in which the inner housing has one or more radially flexible tags which are in communication with the plunger but not the barrel
  - a third position in which said one or more radially flexible tags on the inner housing are in communication with neither the barrel nor the barrel

The problem to be solved by the present invention may therefore be regarded as how to retract in an alternative way the needle into the outer housing after the injection.

No document of the search report discloses a such injection device.
The document D2 discloses an injection device with a retractable needle but without a driving force applied to the flange of the syringe. It is not evident to combine the teachings of D1 and D2 in order to make a retractable needle with several flexible tags in D1.

The subject matter of **claims 1-32** is considered to meet the requirement of Article 33 (1) PCT in respect of novelty and inventive step.

**Re Item VII**
**Certain defects in the international application**

1. Claim 32 contains references to the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

2. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D1 is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

**Certain observations on the international application**

Although **claims 1,29 and 30** have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought.

The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection. Hence, these claims do not meet the requirements of Article 6 PCT.

It appears to be appropriate to file an amended set of claims taking account of the above comments and Article 34(2)(b) PCT. The revelant subject-matter should be defined in a single independent claim followed by dependent claims covering features which are merely optional (Rules 6.3 and 6.4 PCT)

CLAIMS

1. An injection device comprising an outer housing (30) inside which is located

a barrel for holding a volume of a medicament;

a needle (10) at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing (30) but is biased to be normally wholly inside said housing;

a plunger (8), axially moveable within the barrel;

an inner housing (7) intermediate the outer housing and the barrel and plunger; and

an energy source (1; 40) in communication with said inner housing (7),

characterised in that the inner housing (7) is moveable by the energy source between three positions, namely

a first position in which the inner housing has one or more radially flexible tags (7B) which are in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing has one or more radially flexible tags (7A) which are in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said one or more radially flexible tags (7A, 7B) on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

2. An injection device as claimed in claim 1 further comprising a spring housing (41) intermediate the outer housing (30) and the inner housing (7).

3. An injection device as claimed in claim 1 wherein one or more of said tags is located at the end of a resiliently flexible leg.

4. An injection device as claimed in any of the preceding claims wherein one or more of said tags are situated at the rear end of the inner housing and are moveable radially into and out of communication with the plunger.

5. An injection device as claimed in any of claims 2-4 wherein said tags are biased radially inwardly into communication with said plunger, preferably by communication with said spring housing.

6. An injection device as claimed in any of the preceding claims wherein said tags are stored in their relaxed condition, before initiating an injection.

7. An injection device as claimed in any of claims 2-6 wherein each rear tag is moveable out of communication with the plunger when aligned with a corresponding recess in the spring housing.

8. An injection device as claimed in any of the preceding claims wherein each rear tag is substantially T-shaped.

9. An injection device as claimed in any of claims 1-3

wherein one or more of said tags are situated at the forward end of the inner housing and are moveable radially into and out of communication with the barrel.

10. An injection device as claimed in claim 9 wherein said forward tags are biased radially inwardly into communication with said barrel, preferably by communication with said spring housing.

11. An injection device as claimed in claim 9 or claim 10 wherein said forward tags are stored in their relaxed condition, before initiating an injection.

12. An injection device as claimed in any of claims 9-11 wherein each forward tag is moveable out of communication with the barrel when aligned with a corresponding recess in the spring housing.

13. An injection device as claimed in any of claims 9-12 wherein each forward tag is substantially L-shaped.

14. An injection device as claimed in any of the preceding claims wherein said energy source is a compressed gas.

15. An injection device as claimed in any of claims 1-13 wherein said energy source is a spring.

16. An injection device as claimed in any of the preceding claims further including means for allowing the inner housing to move axially only forward with respect to the outer housing.

17. An injection device as claimed in claim 16 wherein said means is an arrangement of serrations, barbs, ratchet teeth or the like intermediate the housings.

18. An injection device as claimed in any of the preceding claims further comprising guide means for guiding, in use, the relative axial movement of the spring and outer housings, the guide means preferably comprising one or more protrusions on said spring housing which, in use, cooperate with corresponding recesses on an interior surface of said outer housing.

19. An injection device as claimed in any of the preceding claims wherein said needle is biased to be normally wholly inside said housing by means of a spring intermediate the barrel and the outer and/or spring housing.

20. An injection device as claimed in any of the preceding claims wherein the needle is removable from said device.

21. An injection device as claimed in any of the preceding claims wherein said needle, barrel and plunger are removable from said device.

22. An injection device as claimed in any of the preceding claims further including a removable needle cover which protects the needle during storage before use.

23. An injection device as claimed in claim 22 wherein said needle cover includes means for pulling a

protective rubber sheath or the like from said needle when said needle cover is removed from the device.

24. An injection device as claimed in claim 23 wherein said pulling means includes a floating rivet intermediate the needle cover and the protective rubber sheath or the like, whereby twisting forces applied to said needle cover are substantially prevented from being transmitted to said rubber sheath or the like.

25. An injection device as claimed in any of claims 22-24 wherein the presence of said needle cover on said device serves as a safety lock, substantially preventing relative forward movement of said outer housing.

26. An injection device as claimed in any of the preceding claims further comprising a viewing window in said barrel aligned with a viewing window in said outer housing such that said medicament can be viewed by a user prior to an injection taking place.

27. An injection device as claimed in claim 26 wherein, in use during an injection, said inner housing moves intermediate said viewing window in the outer housing and said barrel so as to obscure the window in the barrel from the user's view.

28. An injection device as claimed in any of the preceding claims further comprising means for emitting an audible and/or physical indication to a user that the injection is complete.

29. An injection device comprising an outer housing inside which is located

a barrel for holding a volume of a medicament;

a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing;

a plunger, axially moveable within the barrel;

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

characterised in that the inner housing is moveable by the energy source between two positions, namely

a first position in which the inner housing has one or more radially flexible tags which are in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a second position in which said one or more radially flexible tags on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

30. An injection device comprising an outer housing adapted to receive:

a barrel for holding a volume of a medicament;

a needle at one end of the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing; and

a plunger, axially moveable within the barrel, wherein the injection device further comprises:

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source in communication with said inner housing,

characterised in that the inner housing is moveable by the energy source between three positions, namely

a first position in which the inner housing has one or more radially flexible tags in communication with the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second position in which the inner housing has one or more radially flexible tags in communication with the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third position in which said radially flexible tags on the inner housing are in communication with neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

31. An injection device as claimed in claim 29 or claim 30 having all of the features of any of claims 2-28.

32. An injection device substantially as described herein with reference to and as illustrated in any appropriate combination of the accompanying drawings.

P.B.5818 - Patentlaan 2
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| Europäisches Patentamt | European Patent Office | Office européen des brevets |
|---|---|---|
| Generaldirektion 1 | Directorate General 1 | Direction générale 1 |

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Date
08.06.06

| Reference | Application No./Patent No. |
|---|---|
| | 05701985.3 - 2310 PCT/GB2005000223 |

Applicant/Proprietor
The Medical House Plc

**Entry into the European phase before the European Patent Office**

**These notes describe the procedural steps required for entry into the European phase before the European Patent Office (EPO). You are advised to read them carefully: failure to take the necessary action in time can lead to your application being deemed withdrawn.**

1. The above-mentioned international patent application has been given European application No. **05701985.3**.

2. Applicants **without** a residence or their principal place of business in an EPC contracting state may themselves initiate European processing of their international applications, provided they do so before expiry of the 31st month from the priority date (see also point 6 below).

   **During the European phase before the EPO as designated or elected Office, however, such applicants must be represented by a professional representative (Arts. 133(2) and 134(1), (7) EPC).**

   Procedural acts performed after expiry of the 31st month by a professional representative who acted during the international phase but is not authorised to act before the EPO have no legal effect and therefore lead to loss of rights.

   **Please note that a professional representative authorised to act before the EPO and who acted for the applicant during the international phase does not automatically become the representative for the European phase. Applicants are therefore strongly advised to appoint in good time any representative they wish to initiate the European phase for them; otherwise, the EPO has to send all communications direct to the applicant.**

3. Applicants **with** a residence or their principal place of business in an EPC contracting state are not obliged to appoint, for the European phase before the EPO as designated or elected Office, a professional representative authorised to act before the EPO.
   **However, in view of the complexity of the procedure it is recommended that they do so.**

4. Applicants and professional representatives are also strongly advised to initiate the European phase using EPO Form 1200 (available free of charge from the EPO). This however is not compulsory.

5. **To enter the European phase before the EPO**, the following acts must be performed.
(N.B.: Failure validly to do so will entail loss of rights or other adverse legal consequences.)

5.1 If the EPO is acting as **designated** or **elected** Office (Arts. 22(1)(3) and 39(1) PCT respectively), applicants must, within 31 months from the date of filing or (where applicable) the earliest priority date:

a) Supply a translation of the international application into an EPO official language, if the International Bureau did not publish the application in such a language (Art. 22(1) PCT and R. 107(1)(a) EPC).
**If the translation is not filed in time, the international application is deemed withdrawn before the EPO (R. 108(1) EPC).**
This loss of rights is deemed not to have occurred if the translation is then filed within a two-month grace period as from notification of an EPO communication, provided a surcharge is paid at the same time (R. 108(3) EPC).

b) Pay the national basic fee (EUR 170,00) and, where a supplementary European search report has to be drawn up, the search fee (EUR 720,00 ; R. 107(1)(c) and (e) EPC).

c) If the time limit under Article 79(2) EPC expires before the 31-month time limit, pay the designation fee (EUR 80,00) for each contracting state designated (R. 107(1)(d) EPC).

d) If the time limit under Article 94(2) EPC expires before the 31-month time limit, file the written request for examination **and** pay the examination fee (EUR 1490,00 ; R. 107(1)(f) EPC).

e) Pay the third-year renewal fee (EUR 400,00) if it falls due before expiry of the 31-month time limit (R. 107(1)(g) EPC).

If the fees under (b) to (d) above are not paid in time, or the written request for examination is not filed in time, the international application is deemed withdrawn before the EPO, or the contracting-state designation(s) in question is (are) deemed withdrawn (R. 108(1) and (2) EPC). However, the fees may still be validly paid within a two-month grace period as from notification of an EPO communication, provided the necessary surcharges are paid at the same time (R. 108(3) EPC). For the renewal fee under (e) above, the grace period is **six** months from the fee's due date (Art. 86(2) EPC).

For an overview of search and examination fees, see OJ EPO 11/2005, 577 and 03/2006.

5.2 If the application documents on which the European grant procedure is to be based comprise more then ten claims, a claims fee is payable within the 31-month time limit under Rule 107(1) EPC for the eleventh and each subsequent claim (R. 110(1) EPC). The fee can however still be paid within a one-month grace period as from notification of an EPO communication pointing out the failure to pay (R. 110(2) EPC).

6. If the applicant had a representative during the application's international phase, the present notes will be sent to the representative, asking him to inform the applicant accordingly.

**All subsequent communications will be sent to the applicant, or - if the EPO is informed of his appointment in time - to the applicant's European representative.**

7. For more details about time limits and procedural acts before the EPO as designated and elected Office, see the EPO brochure

   How to get a European patent
   Guide for applicants - Part 2
   PCT procedure before the EPO - "Euro-PCT"

   This brochure, the list of professional representatives before the EPO, Form 1200 and details of the latest fees are now all available on the Internet under

   **http://www.european-patent-office.org**

Receiving section

# PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

# PCT

NOTIFICATION OF ELECTION

(PCT Article 31(7) and Rule 61.2)

To:

European Patent Office
Phoenix Support Help Desk
Att. C. Hamm, Room S00G12, P.O. Box 5818
NL- 2280 HV Rijswijk
PAYS-BAS

in its capacity as elected Office

| | |
|---|---|
| Date of mailing *(day/month/year)*<br>08 December 2005 (08.12.2005) | |
| International application No.<br>PCT/GB2005/000223 | Applicant's or agent's file reference<br>P10349WO |
| International filing date *(day/month/year)*<br>24 January 2005 (24.01.2005) | Priority date *(day/month/year)*<br>23 January 2004 (23.01.2004) |
| Applicant<br>THE MEDICAL HOUSE PLC et al | |

1. The designated Office is hereby notified of its election made in the demand filed with the International Preliminary Examining Authority on:
   20 October 2005 (20.10.2005)

2. The election ☐ was
   ☑ was not
   made before the expiration of 19 months from the priority date (PCT Article 39(1)(a)).

| | |
|---|---|
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland<br><br>Facsimile No.+41 22 740 14 35 | Authorized officer<br>Dorothée Mülhausen<br><br>Facsimile No.+41 22 338 87 40 |

Form PCT/IB/331 (January 2004)

# PATENT COOPERATION TREATY



From the INTERNATIONAL BUREAU

## PCT

### NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

HARRISON GODDARD FOOTE
Fountain Precinct
Balm Green
Sheffield S1 2JA
United Kingdom

**Date of mailing** (day/month/year)
07 March 2006 (07.03.2006)

**Applicant's or agent's file reference**
P10349WO

**IMPORTANT NOTIFICATION**

**International application No.**
PCT/GB2005/000223

**International filing date** (day/month/year)
24 January 2005 (24.01.2005)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
THE MEDICAL HOUSE PLC
201 Newhall Road
Attercliffe
Sheffield S9 2QJ
United Kingdom

State of Nationality: GB
State of Residence: GB
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
THE MEDICAL HOUSE PLC
199 Newhall Road
Attercliffe
Sheffield S9 2QJ
United Kingdom

EPO-DG 1
15. 03. 2006
TEAM 14

State of Nationality: GB
State of Residence: GB
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No. (41-22) 338.87.40

Authorized officer
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